2009 H1N1 Influenza
Updated Key Points
December 1, 2009

2009 H1N1 Influenza Vaccine

In this Section:

- Supply
- Recommendations
- Research

Supply

- On November 16, 2009, the Food and Drug Administration (FDA) announced its approval of a fifth vaccine for protection against the 2009 H1N1 flu virus. This vaccine will be manufactured using the same established, licensed egg-based process that is used for producing seasonal flu vaccine and will be produced in multi-dose vials, in a formulation that contains thimerosal. Since this vaccine will not be available for distribution until the end of December, it does not affect current vaccine supply.

- CDC is now posting daily updates of the national totals of 2009 H1N1 vaccine supply status (aggregate number of doses allocated, ordered, and shipped). These numbers are updated by 4 p.m. EST every day and posted at: http://www.cdc.gov/h1n1flu/vaccination/vaccinesupply.htm

- **(Updated)** As of Tuesday, December 1, 2009, a total of 68,985,700 doses were available for ordering. Of those available doses, 52,206,100 doses were injectable (flu shots) and 16,779,600 were LAIV (nasal spray vaccine).

- **(Updated)** As of Monday, November 30, 2009, there were a total of 60,494,600 doses ordered.

- Supplies of 2009 H1N1 vaccine continue to increase. More doses are expected for shipment each week. We ask members of the public who want to receive this vaccine to be patient as this program expands and more vaccine continues to become available.

- The challenges associated with the U.S. influenza vaccine supply are multi-faceted. Influenza viruses change from year to year, so influenza vaccines must be updated annually to include the viruses that research indicates are most likely to circulate in the upcoming season. Once the viruses are selected for the new formulation, manufacturers operate under a very tight timeline for producing, testing, releasing and distributing the vaccine. Due to these time constraints, any problems encountered during production may cause shortages or delays, and in fact, such problems have impacted the seasonal supply during some recent influenza seasons, and can occur with any type of influenza vaccine, including the 2009 H1N1 vaccine.

- The vaccine development process is complex and forecasting how much vaccine will be available at a certain time is challenging and amounts will vary from week to week. Millions of doses of vaccine are in the pipeline and federal, state and local public health authorities are working hard to get vaccine out to the public as soon as it is received.
- It also is important to keep in mind that there will be lag times between states placing orders and vaccine actually being distributed (we are not cutting corners in terms of steps like quality control checks) - and any number of things can create lag times between time of distribution to states and when vaccine actually arrives in provider offices or clinics.
- This vaccine program is a massive and challenging undertaking and is being carried out at a time when state and local health departments have experienced severe budget cuts.
- The federal government allocates vaccine on a pro rata basis to state health departments and some big city health departments who then make decisions about how to distribute vaccine equitably and efficiently within their jurisdictions.
- Employee or workplace health clinics (among other locations) are a legitimate—and very effective—place to administer vaccine during a time of shortage. These clinics can and do reach and target people in priority vaccination groups, including pregnant women and 18 to 64 year workers with medical conditions that put them at higher risk for influenza complications.

Recommendations

- A report in the August 21, 2009, *Morbidity and Mortality Weekly Report* (MMWR) provides official recommendations by CDC's Advisory Committee on Immunization Practices (ACIP) regarding the use of vaccine against 2009 H1N1 influenza. This report is available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm
- The guiding principle of these recommendations is to vaccinate as many persons as possible as quickly as possible with an emphasis on vaccinating certain target groups with initial doses of vaccine.
- These recommendations:

  1) Identify five initial target groups for vaccination efforts comprising an estimated 159 million persons (pregnant women, persons who live with or provide care for infants younger than 6 months, health care and emergency medical services personnel, children and young adults aged 6 months through 24 years, and persons aged 25 through 64 years who

have medical conditions that put them at higher risk for influenza-related complications),

2) Establish a priority subset of persons within the initial target groups in the event that initial vaccine availability is unable to meet demand, and

3) Provide guidance on use of 2009 H1N1 vaccine in other adult population groups as vaccine availability increases.

- The recommendations are broad and allow for flexibility to accommodate local variability in vaccine needs and demands. Providers should be aware of and follow any additional guidance provided by their state or local health departments. If no additional guidance is provided at the state or local level, providers should vaccinate among the initial target group populations on a first come, first serve basis.
- Simultaneous administration of inactivated vaccines (shots) against seasonal and the 2009 H1N1 influenza viruses is permissible if different anatomic sites are used (for example, one vaccine in each arm).
- CDC has no recommendation regarding the administration of acetaminophen or other antipyretic drugs following influenza vaccination. You should follow the guidance of your physician or other health care provider.

Research on Public Knowledge, Attitudes and Beliefs

- A national poll with a representative sample of 1,073 adults aged 18 years and over was conducted by the Harvard School of Public Health (HSPH) on October 30 through November 1, 2009. The poll asked about people's perceptions and experiences of trying to get the H1N1 vaccine for themselves or their children.
- 91% of the polling sample who were unable to get the 2009 H1N1 flu vaccine said that they will try again this year to get the vaccine for themselves, their children or both.
- To view a full report of the Harvard Poll press release, visit http://www.hsph.harvard.edu/news/press-releases/

2009 H1N1 Influenza Vaccine Safety

In this section:
General H1N1 Vaccine Safety
Vaccine Safety Monitoring
Background Rates of Medical Events
Weekly Summary of VAERS Data
VAERS Limitations

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General H1N1 Vaccine Safety

- The 2009 H1N1 vaccine is made the same way as seasonal flu vaccines. Millions of seasonal flu vaccines have been given safely. Millions of people have also safely received the 2009 H1N1 vaccine.
- GlaxoSmithKline has asked the Canadian government to stop using vaccine doses from one particular lot shipment (A80CA007A). Several cases of anaphylaxis, a severe allergic reaction, have been reported and are being investigated among people vaccinated from this shipment.
- The vaccine recalled is not available in the United States.
- Canadian health officials have noticed severe allergic reactions from that lot at a rate of one in 20,000, compared with the standard reaction rate of one in 100,000.
- Getting the 2009 H1N1 influenza vaccine is much safer than getting H1N1 influenza. You can prevent 2009 H1N1 influenza illness by getting the 2009 H1N1 vaccine.
- The benefits of getting the 2009 H1N1 influenza vaccine far outweigh the very small risk of serious complications from vaccination. Some people getting vaccinated will have mild side effects such as pain, redness or swelling in the arm where the shot was given or a runny nose and headache after the nasal spray vaccine.
- CDC expects that the 2009 H1N1 influenza vaccines will have similar safety profiles as seasonal influenza vaccines, which have very good safety track records.
- CDC expects that any serious side effects following vaccination with the 2009 H1N1 influenza vaccine would be rare.
- The types and frequencies of side effects from the 2009 H1N1 influenza vaccine will likely be similar to those experienced following seasonal influenza vaccines which are mild, localized reactions.

Vaccine Safety Monitoring

- HHS released a report on the Federal Plans to Monitor Immunization Safety for the Pandemic 2009 H1N1 Influenza Vaccination Program: http://flu.gov/professional/federal/monitor_immunization_safety.html
- CDC and its partners are using several systems to monitor the safety of 2009 H1N1 influenza vaccine. Two primary systems that are in use are the Vaccine Adverse Event Reporting System (VAERS), which is jointly operated with FDA, and the Vaccine Safety Datalink (VSD) Project.

  - CDC has enhanced vaccine safety monitoring efforts in several ways:

  - The Vaccine Adverse Event Reporting System (VAERS) is a voluntary reporting system that identifies potential vaccine safety signals: healthcare providers are actively reminded to report suspected issues, and medical personnel are conducting daily reviews and follow-up [http://vaers.hhs.gov].

  - Second, a new Web-based active surveillance system is being implemented to prospectively follow tens of thousands of vaccinated people [www.myflushot.org].

  - Third, large population-based systems that link computerized vaccination data with healthcare codes will be used to conduct rapid and ongoing analyses. This approach includes data from large managed care plans, other health plans, Department of Defense, Medicare and the Veterans' Administration.

  - Fourth, active case finding for Guillain-Barré syndrome (GBS) is being conducted in 10 areas of the United States (a combined population of about 50 million people)

  - Findings from all sources are cross-referenced and reviewed by government and outside scientists to be sure any concerns are rapidly addressed.

- Vaccine safety monitoring includes reviewing adverse events reported by providers, manufacturers, people who were vaccinated or their caregivers.

  - An adverse event following immunization is a medical incident that occurs after someone receives an immunization.

  - Adverse events may be coincidental (meaning occurring around the same time but not related to vaccination) or caused by vaccination.

- The purpose of vaccine safety monitoring is timely identification of any clinically significant adverse events following immunization, as well as to provide timely information to the public, vaccine providers, public health officials, and policy makers.

Background Rates of Medical Events

- Adverse events—such as sudden deaths, spontaneous abortions, and Guillain-Barré syndrome—will occur in the population. These will occur whether or not people have been vaccinated. In the context of vaccine

safety monitoring, we call these naturally occurring events "background rates."

- Awareness of the background rates of several adverse events is critical to assessing the safety of the vaccine. This information allows public health and medical experts to identify when adverse events are occurring more frequently than would be expected in the absence of vaccination and need more detailed investigation to determine if the vaccine is causing the adverse events.

- Background rates are helpful as a tool to assess vaccine safety by comparing the expected rate of adverse events to the actual/observed rate in any given timeframe once vaccination begins.

- Some clustering – a number of cases in a limited timeframe or area – of adverse events occurs normally, and we can expect this clustering to continue during the period that 2009 H1N1 vaccinations are given.

- By comparing the expected rate of adverse events to the actual/observed rate in any given timeframe, we can put adverse event reports in proper context.

- There are some limitations of background rates. Background rates can vary widely by location, age, sex and ethnicity, and therefore these factors should be considered when using background rates to compare events that occur following vaccination.

- Background rates by themselves usually are not sufficient as a way to fully assess vaccine safety. Full analysis requires review of individual reports and carefully controlled epidemiologic study.

    - While background rates tell us that we cannot jump to conclusions or assume that any vaccine caused a particular health event, CDC takes every single adverse event report seriously and individually reviews all reports of serious adverse events so that potential problems can be quickly detected and investigated.

Weekly Summary of VAERS Data

CDC and FDA release a weekly report on vaccine safety that provides a summary on adverse event data that are being viewed publicly through VAERS (www.vaers.hhs.org) and CDC's website, WONDER (http://wonder.cdc.gov/vaers.html). These weekly reports can be accessed at: http://vaers.hhs.gov/resources/h1n1update#top.

- The summary includes the number of doses shipped, the number of adverse events reported to VAERS weekly, the percentage of serious adverse event reported, and a general description of serious adverse events. These summaries will also include CDC and FDA actions following reports of serious adverse events.

VAERS Limitations **(Updated)**

- When reviewing data from VAERS, the following limitations should be kept in mind:
    - VAERS is a passive reporting system, meaning that reports about adverse events can be submitted voluntarily by anyone, including healthcare providers, patients, or family members. Because of this feature, VAERS reports may and often do include incorrect and incomplete information. VAERS reports often lead to more complete follow-up and review of medical records.
    - Underreporting, or failure to report events, is also one of the main limitations of VAERS. Serious medical events are more likely to be reported than minor events.
    - Most importantly, **VAERS cannot determine cause-and-effect**. The report of an adverse event to VAERS does not confirm that a vaccine caused the event. It only indicates that the event occurred sometime after administration of the vaccine. Proof that the event was caused by the vaccine is NOT required in order for VAERS to accept the report. VAERS accepts all reports without regard as to whether or not the event was caused by the vaccine.
    - No reports are deleted from VAERS. Therefore, it is possible to have more than one VAERS report on an individual case (e.g., a physician and a patient may have filed separate reports for the same case).
    - For all reports of serious adverse events, VAERS staff collects follow-up records on each case and medical officers review them closely to determine if any additional action or studies are needed.

The most reliable information about vaccine side effects can be found in the manufacturers' vaccine package insert (http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093830.htm), vaccine information statements (VISs), or the Advisory Committee on Immunizations Practices' (ACIP's)

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In this Section:

Seasonal Influenza Vaccine

- Two systems that look at seasonal influenza vaccinations administered and billed show that more individuals have been vaccinated with seasonal vaccine this season than at the same time last year. This is most likely due to the early availability of vaccine and public interest in getting vaccinated.

Seasonal Influenza Vaccine Supply and Distribution

- Due to early availability and high demand of seasonal flu vaccine, limited amounts of seasonal supply remain. At this point, CDC continues to encourage those at highest risk from flu complications to seek seasonal flu vaccine and receive 2009 H1N1 vaccine, as recommended.
- As of November 13, approximately 94.5 million doses of seasonal influenza vaccine have been distributed.
- Local areas may not have received as much vaccine as they anticipated at this point in the season and providers seeking additional vaccine now may be unable to purchase it. For more information about seasonal supply, please refer to IVATS (http://www.preventinfluenza.org/ivats/) over the coming weeks.
- More information about seasonal flu vaccine supply can be found at: http://www.cdc.gov/flu/professionals/vaccination/#supply

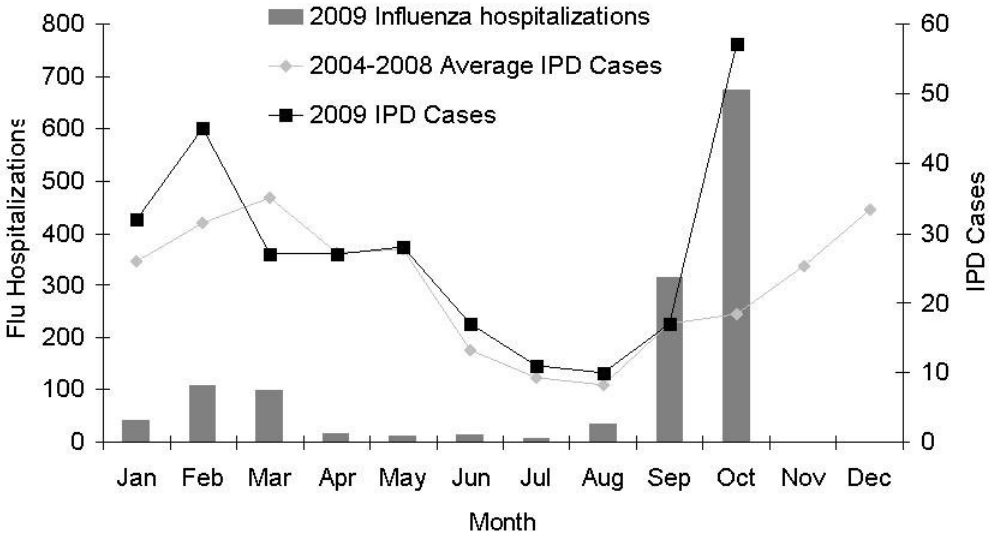
Increase in Invasive Pneumococcal Disease

- Some of CDC's Active Bacterial Core surveillance (ABCs) sites have seen an increase in serious cases of pneumococcal disease coincident with increases in influenza-associated hospitalizations. CDC has been working with state and local public health officials in Colorado for example concerning its ABCs site in the Denver Metro area to collect additional data on pneumococcal disease cases.
- There is good evidence that 2009 H1N1 influenza may be responsible for this increase in invasive pneumococcal disease (IPD) cases in the Denver Metro area. (5-year average number of cases in October, ~20; total number in October 2009, 58).
- The increase in IPD cases in the Denver Metro area is primarily among younger adults with 36 out of 58 (62%) cases occurred among 20-59

year olds. In a typical non-pandemic year, most IPD cases occur among persons 65 years of age and older.

- Data shown below in the graph are preliminary and subject to change upon further investigation.
- For more information on preventing pneumococcal infections secondary to seasonal and 2009 H1N1 influenza: http://www.cdc.gov/h1n1flu/vaccination/public/public_pneumococcal.htm

Influenza Hospitalizations & Invasive Pneumococcal Cases, All Ages, Denver Metro, Provisional 2009 (year-to-date) vs. 5 -Year Average (2004-2008)



*Denver Metro includes Adams, Arapahoe, Denver, Douglas, and Jefferson Counties

Data courtesy of K. Gershman, Colorado Emerging Infections Program & Influenza Division, CDC

Flu Activity May Occur in "Waves"

- The timing, spread and severity of influenza viruses is uncertain.
- Outbreaks of influenza may occur in different places at different times.
- Outbreaks may occur in waves of about 6-12 week time periods.
- These waves of influenza may occur over a year or so after the emergence of a new influenza virus.
- In past pandemics, "waves" of activity have been observed.

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- The first wave is usually a smaller wave; followed by a larger "peak" wave. Subsequent smaller waves can occur as well.
- The United States experienced its first wave of 2009 H1N1 pandemic activity in the spring of 2009.
- At this time, we are experiencing a second wave of 2009 H1N1 activity.
- Flu activity is widespread in most of the country at this time, which is highly unusual during regular seasonal flu for this time of year, but not unexpected for a pandemic.
- Even after flu activity peaks during the current wave, it's possible that other waves of influenza activity may occur – caused by either 2009 H1N1 viruses or regular seasonal flu viruses.
- Because the timing and spread of influenza viruses are unpredictable, CDC is continuing to recommend vaccination with seasonal influenza vaccine and 2009 H1N1 vaccine for those people in whom it is recommended.